

EXHIBIT B

Authors' response to "malignant mesothelioma following exposure to cosmetic talc: Association, not causation"

To the Editor,

We appreciate the opportunity to reply to Dr. Geyer's letter.

Geyer has commented on possible "recall-bias" in our paper. We should note that we began with a series of 140 patients which was reduced to 75 when we excluded those where a history of other asbestos exposures were present. In legal cases, experts supporting both the plaintiffs and the defense regularly search for all exposures to asbestos. If, in our series, an odd case or two without such recollection may have been included, then there would still be an abundance of cases to support our findings.

Geyer commented that the methods section "provides no descriptions of analysis of any cosmetic talc products used by any individual included in the study and, thus, the methods give no analytical evidence or data demonstrating that any of their 75 study patients used any cosmetic talcum powder that contained asbestos". By implication, Geyer is suggesting that there is no evidence that asbestos was present in talc or that it caused the mesotheliomas we report. In this regard, Geyer and readers can refer to the recently published article by Steffen et al¹ which details methodology used to determine the presence of asbestos in cosmetic talcum powder. Furthermore, according to Geyer one might surmise that talc alone is capable of producing mesothelioma, although no regulatory agency to our knowledge currently accepts that premise, and it begs imagination to conclude that the 75 mesotheliomas in this series were all "idiopathic," in the face of compelling evidence of asbestos contamination of talc.

We recognize that a case series does not in itself "prove" causation. Indeed, causation is never proved except via the strength of association. The strength of association between the development of mesothelioma and exposure to amphibole asbestos has been established. As no safe threshold has been established for exposures to asbestos and the development of mesothelioma,² it is reasonable to suggest that repeated exposures above background to low-levels of asbestos are causal of this disease without the need for a case-controlled epidemiological study. The only role of the latter might be to determine risk prospectively in a large exposed population.

Our study is a case series of patients who developed mesothelioma, and whose only known exposure to asbestos was through cosmetic talc. Case reports and case series can be critical in advancing our knowledge of disease. Wagner's case series of 33 cases of malignant mesothelioma from the mines of South Africa in 1960³ was generally accepted as convincing evidence that asbestos was the cause of this rare disease. The

present study of 75 cases, together with Moline's 33 reported cases,⁴ supports the generally accepted notion that amphibole asbestos is a cause of malignant mesothelioma, due to asbestos contamination of cosmetic talc.

Geyer's comment regarding fiber size is misleading. The 3:1 aspect ratio with supporting microprobe analysis is generally accepted as the morphological definition of an asbestiform fiber by OSHA, the EPA, and other international regulatory agencies.⁵⁻⁷ The comments concerning the laboratory methods, and the implication that they were not controlled for contamination, has been leveled against many laboratories without convincing evidence.

Geyer also questions whether experts for the defense performed similar or equivalent testing. While we are unaware of other testing performed for these cases, we are aware that certain methods, including scanning electron microscopy, have a low sensitivity for detecting low levels of asbestos contamination. Indeed, in our own study we excluded such evidence in the final reporting of the data.

Although Geyer states that he finds no evidence to support our suggestion "that cosmetic talc may cause malignant mesothelioma", this paper is only one piece of ever-growing evidence, including the conclusion by IARC,⁸ that this is the case.

Our series of 75 additional individuals with malignant mesothelioma whose only known exposure was cosmetic talc is further evidence that cosmetic talc should be considered a probable cause of mesothelioma. Due to the lethality of malignant mesothelioma, regulation or removal of talc-based products from the market is warranted in the interest of public safety, as other nontoxic alternatives are available.

CONFLICTS OF INTEREST

Theresa S. Emory, John C. Maddox, and Richard L. Kradin have testified in asbestos litigation, primarily for plaintiffs.

DISCLOSURE BY AJIM EDITOR OF RECORD


John D. Meyer declares that he has no conflict of interest in the review and publication decision regarding this article.


AUTHOR CONTRIBUTIONS

JCM and RLK developed the conception and the design of the work. JCM initiated the acquisition and developed the initial data analysis. TSE reviewed the materials, performed the statistical analysis and was the primary author of the manuscript. RLK revised and gave final approval of the version to be published.

ETHICS APPROVAL AND INFORMED CONSENT

As these cases were selected from medical-legal consultation practice and no identifying information is included, there was no formal institutional consent nor informed consent required.

Theresa S. Emory MD¹ 

John C. Maddox MD¹ 

Richard L. Kradin MD^{2,3} 

¹Peninsula Pathology Associates, Department of Pathology, Riverside Regional Medical Center, Newport News, Virginia

²Department of Medicine (Pulmonary/Critical Care), Massachusetts General Hospital, Boston, Massachusetts

³Department of Pathology, Massachusetts General Hospital, Boston, Massachusetts

Correspondence

Theresa S. Emory, MD, Peninsula Pathology Associates
Department of Pathology 500 J Clyde Morris Boulevard, Newport News, VA 23601.

Email: temorymd@gmail.com

ORCID

Theresa S. Emory  <http://orcid.org/0000-0002-8075-4480>

John C. Maddox  <http://orcid.org/0000-0003-1417-0337>

Richard L. Kradin  <http://orcid.org/0000-0002-3953-8671>

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